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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/512,731	10/26/2004	Daniel W. Chan	57222(71699)	1716

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EXAMINER	
RAWLINGS, STEPHEN L	
ART UNIT	**PAPER NUMBER**
1643	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	03/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/512,731	CHAN ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,30,31,42 and 43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-12,30,31,42 and 43* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed October 26, 2004, is acknowledged and has been entered. Claims 13-29, 32-41, and 44-77 have been canceled. Claims 11 and 12 have been amended.

2. Claims 1-12, 30-31, 42, and 43 are pending in the application and are currently subject to restriction.

Election/Restrictions

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I. Claim(s) 5, insofar as the claim is drawn to a method of qualifying prostate cancer status in a subject, said method comprising measuring at least one biomarker in a sample from the subject, wherein said prostate cancer status is the subject's risk of cancer.

Group II. Claim(s) 5, insofar as the claim is drawn to a method of qualifying prostate cancer status in a subject, said method comprising measuring at least one biomarker in a sample from the subject, wherein said prostate cancer status is the presence or absence of disease.

Group III. Claim(s) 5, insofar as the claim is drawn to a method of qualifying prostate cancer status in a subject, said method comprising measuring at least one biomarker in a sample from the subject, wherein said prostate cancer status is the type of disease.

Group IV. Claim(s) 5, insofar as the claim is drawn to a method of qualifying prostate cancer status in a subject, said method comprising measuring at least one biomarker in a sample from the subject, wherein said prostate cancer status is the stage of disease.

Group V. Claim(s) 5, insofar as the claim is drawn to a method of qualifying prostate cancer status in a subject, said method comprising measuring at least one biomarker in a sample from the subject, wherein said prostate cancer status is the effectiveness of treatment of disease.

Group VI. Claim(s) 6, drawn to a method for differentiating between diagnoses of prostate cancer and non-prostate cancer, said method comprising detecting an amount of at least one biomarker in a sample from a subject.

Group VII. Claim(s) 7, drawn to a method for differentiating between diagnoses of prostate cancer and benign prostate hyperplasia, said method comprising detecting an amount of at least one biomarker in a sample from a subject.

Group VIII. Claim(s) 8, drawn to a method for differentiating between diagnoses of prostate cancer and benign prostate hyperplasia, said method comprising detecting an amount of at least one biomarker in a sample from a subject.

Group IX. Claim(s) 9, drawn to a method for differentiating between diagnoses of organ defined prostate cancer and non-organ defined prostate cancer, said method comprising detecting an amount of at least one biomarker in a sample from a subject.

Group X. Claim(s) 10, drawn to a method for differentiating between diagnoses of organ defined prostate cancer and non-organ defined prostate cancer, said method comprising detecting an amount of at least one biomarker in a sample from a subject.

Group XI. Claim(s) 30 and 31, drawn to a kit.

Group XII. Claim(s) 42, drawn to a protein.

Group XIII. Claim(s) 43, drawn to a plurality of proteins.

4. Claim 1-4, 11, and 12 are linking claims, linking the inventions of I, II, III, and IV. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

5. The inventions listed as Groups I-XIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of the invention of Group I is qualifying the subject's risk of cancer by a process comprising measuring at least one biomarker in a sample from the subject.

The special technical feature of the invention of Group II is qualifying the presence or absence of disease in a subject, said method comprising measuring at least one biomarker in a sample from the subject.

The special technical feature of the invention of Group III is qualifying the type of disease in a subject, said method comprising measuring at least one biomarker in a sample from the subject.

The special technical feature of the invention of Group IV is qualifying the stage of disease in a subject, said method comprising measuring at least one biomarker in a sample from the subject.

The special technical feature of the invention of Group V is qualifying the effectiveness of treatment of disease, said method comprising measuring at least one biomarker in a sample from the subject.

The special technical feature of the invention of Group VI is differentiating between diagnoses of prostate cancer and non-prostate cancer, said method comprising detecting an amount of at least one of the biomarkers, as identified in the claims, in a sample from a subject.

The special technical feature of the invention of Group VII is differentiating between diagnoses of prostate cancer and benign prostate hyperplasia, said method comprising detecting an amount of at least one of the biomarkers, as identified in the claims, in a sample from a subject.

The special technical feature of the invention of Group VIII is differentiating between diagnoses of prostate cancer and benign prostate hyperplasia, said method comprising detecting an amount of at least one of the biomarkers, as identified in the claims, in a sample from a subject.

The special technical feature of the invention of Group IX is differentiating between diagnoses of organ defined prostate cancer and non-organ defined prostate cancer, said method comprising detecting an amount of at least one of the biomarkers, as identified in the claims, in a sample from a subject.

The special technical feature of the invention of Group X is differentiating between diagnoses of organ defined prostate cancer and non-organ defined prostate cancer, said method comprising detecting an amount of at least one of the biomarkers, as identified in the claims, in a sample from a subject.

The special technical feature of the invention of Group XI is making a kit.

The special technical feature of the invention of Group XII is making a protein.

The special technical feature of the invention of Group XIII is making a plurality of proteins.

Accordingly, the inventions of Groups I-XIII do not share the same or corresponding special technical feature so as to form a single general inventive concept under PCT Rules 13.1 and 13.2.

6. With further regard to the invention of Group XII, *claim 42 is not generic,* but is drawn to any one of plurality of patentably distinct proteins, wherein said protein is any one of the different biomarkers recited in the claim.

Accordingly, if Applicant elects the invention of Group XII, Applicant is further required to identify the protein to which the claim is to be directed by identifying one of the biomarkers identified in the claim to which the claim is to be directed during prosecution, and to which the claim shall be restricted.

The inventions of Groups XII do not share the same or corresponding special technical feature so as to form a single general inventive concept under PCT Rules 13.1 and 13.2 because each protein is distinct from each of the others.

7. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

(a) Claim(s) 1-5, 11, and 12, are drawn to patentably distinct species of one of the inventions of Groups I-V, wherein said process comprises measuring any one or more different biomarkers.

Accordingly, Applicant is require to identify the species of the invention by identifying the one or more biomarkers identified in claim 42 to which the claims are to be directed during prosecution, and to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner notes that to the extent that claims are drawn to a novel and nonobvious species of invention, the claims are allowable over the prior art but not necessarily over the requirements set forth under 35 U.S.C. §§ 101 and 112.

(b) Similarly, claim(s) 6-10, are drawn to patentably distinct species of the inventions of Groups VI-X, respectively, wherein said process comprises detecting or quantifying any one or more different biomarkers.

Accordingly, Applicant is require to identify the species of the invention by identifying the one or more biomarkers identified in claims 6-10 to which the claims are to be directed during prosecution, and to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner notes that to the extent that claims are drawn to a novel and nonobvious species of invention, the claims are

allowable over the prior art but not necessarily over the requirements set forth under 35 U.S.C. §§ 101 and 112.

(c) Claim(s) 30 and 43, are drawn to patentably distinct species of the inventions of Group XI and XIII, respectively, wherein said kit or plurality comprises any one or more different biomarkers.

Accordingly, Applicant is require to identify the species of the invention by identifying the one or more biomarkers identified in claims 30 (Group XI) and 42 (Group XIII) to which the claims are to be directed during prosecution, and to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner notes that to the extent that claims are drawn to a novel and nonobvious species of invention, the claims are allowable over the prior art but not necessarily over the requirements set forth under 35 U.S.C. §§ 101 and 112.

8. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

9. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The special technical feature of any one of the different species of any one of the different inventions is different from the special technical features of any other because each species is a process comprising detecting or quantifying one or more different

biomarkers, or a process comprising making a product comprising one or more different biomarkers.

Accordingly, none of the different species of any of the different inventions share the same or corresponding special technical feature so as to form a single general inventive concept under PCT Rules 13.1 and 13.2.

10. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is

(571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Primary Examiner
Art Unit 1643

slr
March 21, 2007